REMARKS / ARGUMENTS

I. Amendments to the Specification

The Specification has been amended to correct obvious typographical errors. Additionally, the patent number of a patent referred to in the Background of the Invention section has been corrected. New paragraphs representing a summary of the claims filed with the original application have been added to the Summary of the Invention section. No new matter has been added.

II. Claim Objections

Claims 15, 17-19, and 21-29 are pending in this application.

Claim 28 has been rejected under 35 U.S.C. §112, second paragraph as failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. In particular, the examiner concluded that the limitation, "means for transmitting voice and data," lacked an antecedent. Applicant directs the examiner to claim 15 to which claim 28 depends. Claim 15 recites the limitation "wherein said plurality of ICU's include means for transmitting voice and data to said remote command center by the at least one network."

The examiner also found that the use of the "means for" language in various claims did not invoke 35 U.S.C. §112 6th paragraph. Applicants submit that the "means for" language was intended to invoke 35 U.S.C. §112 6th paragraph and that the recitation of any structure beyond the function "to transmit voice and data," such as "remote command center" and "network" in the "means for transmitting voice and data to said remote command center by the at least one network" are used only to refer to the interrelation of the "means" to the previously claimed "remote command center" and "network." As such, Applicants desire to invoke 35 U.S.C. §112 6th paragraph and respectfully request examination of the claims accordingly.

III. Obviousness Rejections

A. Generally

Various claims of the present invention have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 3,646,606 issued to *Buxton* et al. (herein "Buxton") or U.S. Patent 6,364,834 issued to *Reuss*, et al. (herein, "Reuss") in view of U.S. Patent 4,838,275 issued to Lee (herein, "Lee").

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP. §2142 (8th Ed , Rev. 1). The references and the applicant's disclosure must be considered as a whole. MPEP §2142.02 (8th Ed., Rev. 1).

In order to appreciate the teachings of the cited references and the present invention, it is important to establish what is meant by certain words and phrases as they are used in the references and the application. "Monitoring" connotes the collection of data, but does not convey precisely what is done with the gathered data. The Nenov, et al. reference cited by the examiner illustrates this point. Following numbered paragraph 2, Nenov describes two systems, one for "continuous EEG monitoring... and the second ... devoted to continuous monitoring of physiological parameters..." Nenov describes what happens to the data gathered by the monitoring systems: "Typically, these data are displayed on a computer monitor, spot checked by nurses and lost as it scrolls off the screen." *Continuous monitoring* does not equate to *continuous evaluation* of the data collected by the monitoring systems or the production of highly processed information about patients.

Buxton, Reuss, and Lee each describe some level of data collection. Considered as a whole, these references each set out to solve a health care related problem. Reuss defines the problem in terms of communication:

> There remains a need, therefore, for an integrated medical monitoring system which provides bi-directional, wide bandwidth communications between a number of elements including patient monitors, central monitoring systems, medical alert systems, and analysis systems to allow both monitoring and sharing of collected data for data intensive physiological parameters and waveforms. Reuss, col. 2, lines 47-63.

Buxton substantially shares this view:

> However, a number of problems exist with respect to existing apparatus, particularly in the area of interface between measurement equipment and the medical observer who must, with a high degree of efficiency, extract measured

data and act on it. A further problem area lies in presently used means for communicating data between a person and the data readout equipment. Buxton, col. 1, lines 9-15.

Lee defines a problem of obtaining diagnostic services for ambulatory, house-bound patients:

> Historically, people in acute physical distress were visited in their homes by physicians who diagnosed medical problems with the aid of a few simple, crude instruments. With the advent of modern sophisticated diagnostic techniques and equipment, house calls were discontinued.
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> People in medical distress now must go to the physician's office or to a hospital emergency room for treatment. Adding insult to injury, the patient must often go to another facility such as a specialist's office or a testing laboratory, since the diagnostic equipment in most physicians' offices is insufficient for many diagnoses, especially of cardiovascular malfunctions.
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> Thus the patient while already ill--and often partly incapacitated--must travel repeatedly and sometimes on short notice to several health-care professionals. Not only does this frequently entail great effort, discomfort and cost, but in addition the stress of these efforts often accelerates the decline of the patient's health, further increasing the cost of medical care. Lee, col. 2, lines 30-50.

These references share the belief that if only physiological data can be delivered to the right person, the health of patients would be improved. Thus, each addresses means for gathering physiological data and distributing that data to a location or locations. This is a data-gathering paradigm that makes data available to experts. While the inventions may offer solutions to the problems set forth above, the references teach little more than extending the basic bedside monitoring and data collection to remote locations.

As Applicant has maintained throughout this prosecution, data collection and dissemination is not the only problem identified and addressed by the claimed inventions. Rather, the claimed inventions address the need for providing care for the critically ill that maximizes the presence of an intensivist trained in the care of the critically ill, standardizes the care in ICUs at a high level, and reduces the mortality rate of patients being cared for in ICUs. The claimed inventions accomplish these objectives through automated and intensivist-directed evaluation of the data collected to produce information that can be used to determine whether an intervention with a patient is need and the precise nature of that intervention.

Buxton, Reuss, and Lee are the dominant references cited against the rejected claims. Applicant submits that the motivation to combine these references cannot be found in the

references themselves, but is inspired by the teaching of Applicant's disclosure. The courts have recognized that such hindsight is not permissible:

> "It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Applicant's application have been fruitful is evident by the results achieved where the teachings have been practiced:

> "This system has shown it can save the life of more than one patient per week in two separate intensive care units," says Steven A. Fuhrman, M.D., Sentara Medical Director for the eICU center. "The eICU system shows us each day what happens when you merge the best technology with the most qualified medical professionals."
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> The eICU technology by VISICU efficiently manages scarce intensivist resources while also helping to meet recently defined Leapfrog standards of quality care giving. The Leapfrog Group was formed by Fortune 500 companies and other large healthcare purchasers to monitor patient safety. Hospitals around the country are committed to meeting higher standards of care giving, including providing board certified intensivists to manage the ICU.
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> The eICU system has already been extremely successful in reducing mortality rates at other Sentara facilities. An independent study performed by Cap Gemini, Ernst & Young (CGEY) shows the eICU solution reduced intensive care mortality rates at Sentara Norfolk General Hospital by 25% and shortened the average length of stay for these patients by 17%. This study also revealed that Sentara's per patient costs dropped $2,150 based on reduced patient expenses and increased ICU capacity.
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> Mortality rates plunged when our around the clock reaction time became a matter of seconds," says Rod Hochman, M.D., Senior Vice President and Chief Medical Officer for Sentara Healthcare. "Nothing that we have seen to date has so dramatically altered the quality of care for intensive care patients. Press Release, dated November 17, 2003, issued by Sentara Healthcare, ("Sentara Adds eICU® Technology to Fourth Hospital - Patients at Sentara Leigh Hospital's Intensive Care Units Now Under Lifesaving Care.")

The value of continuous evaluation of patient data according to the teachings of Applicant's disclosure is clearly apparent. The dramatic results achieved by the practice of Applicant's inventions underscore that one skilled in the art, at the time these inventions were made, "who is presented only with the references, and who is normally guided by the then-

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accepted wisdom in the art" would not have been motivated to combine the references to produce the teachings of Applicant's disclosure.

Even assuming that one skilled in the art were motivated to combine the references as suggested by the examiner, regardless of the how the references are combined, the combination will not successfully produce the results of the claimed inventions. This statement is supported, if not proven, by the dramatic and unexpected results derived from practicing the teachings of Applicants disclosure as describe above.

Another substantive issue that is relevant to this analysis is the meaning of "proactive" in the context of a patient emergency. Determining that an emergency has occurred based on the preset threshold of a single physiological parameter and issuing an alarm is an event-driven process, not a "proactive" one. Knowing that a patient has entered an emergency state is not the same as "knowing" that a patient will enter an emergency state at some point in the future if some proactive intervention is not initiated. Further, using trending data that is acquired and saved over hours of monitoring time does not qualify as proactive. As will be discussed below, the proactive aspects of the claimed inventions envision real-time, continuous analysis of data from various sources on a 24-hour, 7-day per week basis.

B. Claims 15, 17, 18 and 19

Claims 15 and 18 of the present invention have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 3,646,606 issued to *Buxton* et al. (herein "Buxton") or U.S. Patent 6,364,834 issued to *Reuss*, et al. (herein, "Reuss") in view of U.S. Patent 4,838,275 issued to Lee (herein, "Lee"). Claim 17 has been rejected as being unpatentable over Reuss in view of Lee. Applicant submits that for the reasons provided below, claims 15, 17, 18 and 19 of the present invention are not obvious in view of the cited references.

Claim 15 of the present invention as amended recites the following limitations:

> A system for providing continuous and proactive expert network health care services from a remote location comprising:
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> a plurality of geographically dispersed ICUs ;
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> a single remote intensivist managed healthcare command center for managing healthcare at said plurality of ICU's; and
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> at least one network;
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> wherein said plurality of ICU's include means for transmitting voice and data to said remote command center by the at least one network,

and wherein said remote command center further comprises at least one intensivist workstation connected to a computerized patient care management system adapted for proactive monitoring and intervention for individual patients at any of said plurality of geographically dispersed ICU's 24 hours per day, seven days a week, triggered by evidence-based data-driven feedback.

In the rejection of claim 15, both Buxton and Reuss were cited as disclosing remote monitoring of critically ill patients. The limitation of "a plurality of geographically dispersed ICUs was equated to Buxton's disclosure of a plurality of intensive care patient units (Buxton Fig. 1-10) and to its disclosure that "patients may be in separate room, making unnecessary a special location for patients requiring intensive care." Buxton, Col. 2, lines 21-24. Reuss was also as cited as teaching a plurality of critical care patient monitors. (Reuss, Fig. 1-16; Reuss, Col. 5, lines 8-10; Reuss, Col. 7, lines 15-25.) The critical care patient monitors were found to be the equivalent of Applicant's ICUs. Applicant acknowledges that the present invention may be practiced to provide proactive monitoring and intervention for the critically ill patients, whether they are in separate room, separate hospitals, or separate countries, accepts the broad interpretation of the stated limitation. Applicant does not, however, accept that the cited references teach the proactive monitoring of the claimed inventions.

The examiner found Buxton and Reuss described proactive monitoring as recited in claim 15 of the present invention. This finding was based on the following language of Buxton:

> In the "Every Patient Continuous Monitoring" section there is continuous monitoring of ... preshock indications. There is selectable continuous monitoring of any of several conditions. Buxton, Col. 2, lines 29-33.

Buxton further defines the function performed by the "Every Patient Continuous Monitoring" section:

> This permits the preset of critical limits for a given patient as determined by his doctor and thus provides selective critical care for that patient. As a still further aid to the detection of a dangerous change in heart condition, a heart signal output...is fed to preshock detector and alarm 78, which detects the presence of higher than normal voltages and energizes alarm light 79. Buxton, Col. 4, lines 5-11.

What is described and taught by Buxton is not proactive monitoring. Rather, static presets are established manually and alarms issued if these presets are exceeded. The alarm is evidence that a dangerous condition is present (e.g., the presence of higher than normal voltages), not that such a condition may occur in the future. There is nothing "proactive" about

this kind of single event-driven process. The inventors of Buxton characterize their invention as follows:

> The operator of the central control monitor visually scans periodically the traces on a cathode-ray display **12** corresponding to the physiological functions of each patient. The operator periodically selects between physiological signals to be observed by selector switch **80**. The operator observes heart rate on a meter **72** and systolic and diastolic blood pressure on meters **81**. Dangerous blood pressure excursions are indicated by preset warning lights **82** and **83** and preshock condition by alarm **78**. When desired, for example, where there is indication of progressive changes in a patient, particular functions may be recorded on tape recorder **90**.
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> The operator may also selectively observe decimal readouts for precise determination of blood pressure, for any patient. In addition, both external and internal temperature are made digitally available for examination.
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> In summary, by means of reasonable attention and selection a single operator is able to provide intensive and extensive observation of a number of patients, a feat not previously possible. Buxton, Col 5, lines 11-31.

Buxton is clearly a data gathering system combined with a single event driven process to manage "emergencies." Data is presented to a single operator and, except for certain alarm conditions, the evaluation of that data is charged to the single operator. Applicant further submits that it is not possible for a single operator to make simultaneous, continuous, proactive evaluations of multiple patients in real-time using the system and methods taught by Buxton. See, the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz. Indeed, Buxton merely subscribes to the ordinary monitoring paradigm employed presently in the majority of hospitals.

In comments directed to Buxton, the examiner concluded, "24/7 is another way of stating 'continuous' monitoring; further [it] is inherent that every ICU is staffed 24/7 and that once an alarm or warning is triggered in an ICU monitoring system intervention would occur, even if it is only to comply with a DNR and note time of death." Taking this conclusion at face value, the examiner is describing an all too common scenario: a patient receives intervention only when an alarm is sounded, and often that is too late. Claim 15 of the present invention is directed to providing "a computerized patient care management system adapted for proactive monitoring and intervention for individual patients at any of said plurality of geographically dispersed ICU's 24 hours per day, seven days a week, triggered by evidence-based data-driven feedback." Claim 15 is directed to providing continuous evaluation of multiple, interrelated factors to permit intervention long before a patient enters an emergency state that is life threatening.

It is well established that "a prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention." In re Geisler, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). Buxton implicitly teaches against the "a computerized patient care management system adapted for proactive monitoring and intervention" recited by claim 15 of the present invention. Rather, Buxton teaches observation of patients by an operator and evaluation of data by an operator. This is not the automated proactive monitoring and intervention limitation of claim 15 of the present invention.

Reuss also describes a central monitoring system that continuously monitors "incoming data for possible emergency situations." When an emergency situation is found, an alert is issued. Reuss, Col. 4, lines 42-48. Reuss does not, however, describe the parameters of an emergency situation, but its clear meaning is that the patient has entered a state of high risk. Emergency handling is an event driven process that occurs after the fact.

Reuss also describes the trending of parameters:

> Comprehensive trending of such parameters as heart rate, blood pressure, SpO.sub.2, respiration rate, etc. over time is available through the Trend Display Manager 55. A 24-hour trending capability is preferred. The trending can involve single or multiple parameters and is especially useful for cardiorespiratory patients, or those with other cardiovascular abnormalities. The Patient, Event, and Trend Managers together comprise the System Executive Task 208. Reuss, Col. 9, lines 38-46.

How the trended data is used is not described. Moreover, Reuss contemplates trending individual physiological parameters. The preferential period is 24 hours. While trending of individual parameters is useful, it should not be confused with the "computerized patient care management system adapted for proactive monitoring and intervention for individual patients ...triggered by evidence-based data-driven feedback" recited by claim 15 of the present invention:

> Referring to Figure 19 the smart alarms of the present invention are illustrated. The smart alarm system constantly monitors physiologic data (collected once per minute from the bedside monitors) and all other clinical information stored in the database (labs, medications, etc). The periodicity of the collection of data is stated for illustrative purposes only. It is well within the scope of the present invention to collect physiological data at more frequent time intervals. Thus, monitor 636 provides information in HL7 form to the interface engine 638. The physiological data is then formatted by the interface engine for storage in the database 640 where all patient information is maintained. **The**

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rules engine 642 searches for patterns of data indicative of clinical deterioration.

One family of alarms looks for changes in vital signs over time, using pre-configured thresholds. These thresholds are patient-specific and setting/disease-specific. For example, patients with coronary artery disease can develop myocardial ischemia with relatively minor increases in heart rate. Heart rate thresholds for patients with active ischemia (e.g. those with unstable angina in a coronary care unit) are set to detect an absolute heart rate of 75 beats per minute. In contrast, patients with known coronary artery disease in a surgical ICU have alarms set to detect either an absolute heart rate of 95 beats per minute or a 20% increase in heart rate over the baseline. For this alarm, current heart rate, calculated each minute based on the median value over the preceding 5 minutes, is compared each minute to the baseline value (the median value over the preceding 4 hours). **Physiologic alarms can be based on multiple variables.** For example, one alarm looks for a simultaneous increase in heart rate of 25% and a decrease in blood pressure of 20%, occurring over a time interval of 2 hours. For this alarm, thresholds were initially selected based on the known association between changes in these two variables and adverse clinical events. Actual patient data were then evaluated to determine the magnitude of change in each variable that yielded the best balance between sensitivity and specificity. This process was used to set the final thresholds for the rules engine.

Alarms also track additional clinical data in the patient database. One alarm tracks central venous pressure and urine output, because simultaneous decreases in these two variables can indicate that a patient is developing hypovolemia. Other rules follow laboratory data (e.g. looking for need to exclude active bleeding and possibly to administer blood).

The purpose of the rules engine is to facilitate detection of impending problems and to automate problem detection thereby allowing for intervention before a condition reaches a crisis state. Application, page39, line 15, through page 40 line 23 (emphasis added by bolding).

As with Buxton, Reuss does not teach automated proactive monitoring:

> The central monitoring system comprises a display, a transceiver or a transmitter and a receiver, and memory storage for storing patient data. The central monitoring system receives data from the local patient monitors, displays this information to caregivers at the central monitor, and stores the data for archival and analysis purposes. Reuss, col. 4, lines 21-27.

And,

> Preferably, the medical monitoring system also comprises at least one auxiliary system for transmitting and receiving clinical data, thereby providing a more complete overall medical monitoring and recordation system. The auxiliary system can be connected to the medical monitoring system via a hardwired network link, or through a wireless communication link. The auxiliary equipment can comprise a diagnostic workstation such as an ECG diagnostic workstation, a

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> clinical information system, or other database system. Diagnostic workstations receive selected archived physiological data such as vital sign data, waveforms, timed cardiac events, or other events from the central monitoring system or a patient monitor for further clinical analysis by a caregiver. Reuss, Col. 6, lines 9-22.

And,

> As mentioned above and as shown in the figures, the present invention can include an automated data acquisition and/or storage component. Such a component, in its various embodiments, can without limitation be incorporated for use in conjunction with the clinical analysis of transmitted data. Reuss, Col. 7, lines 59-63.

While Reuss describes automation of data acquisition, the analysis of the transmitted data is performed post hoc and by a caregiver. As in the case of Buxton, Reuss teaches away from the "a computerized patient care management system adapted for proactive monitoring and intervention" recited by claim 15 of the present invention. Additionally, Reuss contemplates that intervention may not, in fact occur. One of the described capabilities of the Reuss invention is the ability to "determine the location of a plurality of caregivers and select an appropriate primary recipient of the alarm message based on location." Reuss, col.5, lines 47-49. This suggests that while patient data is acquired, it may not be acted upon. This reading is bolstered by references to the bi-directional capabilities of the communications link, "which can determine that a caregiver has read and responded to a message." Reuss, col. 5, lines 3-5.

It is clear that Reuss is directed to information gathering and distribution, not to the automated proactive monitoring and intervention limitation recited in claim 15 of the present invention. Rather, Reuss teaches observation of patients by a caregiver and evaluation of single stream of data by a caregiver.

Applicant submits that both Buxton and Reuss teach against the present invention and are not prior art for the purposes of establishing a prima facie case of obviousness as directed to claim 15 of the present invention. Even if such references were deemed proper, neither Buxton nor Reuss teach a computerized system adapted for proactive monitoring and intervention triggered by evidenced-based data-driven feedback.

It is clear that the PTO's own rules regarding the proper interpretation of claims (see, generally, MPEP §2111 (8th Ed., Rev. 1)) have not been followed in this instance. These rules, which are revised to reflect the rulings of the Federal Courts, are based on the following

principles:

- "During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). See, MPEP §2111, p. 2100-46, (8th Ed., Rev. 1).
- "The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) See, MPEP §2111, p. 2100-47 (8th Ed., Rev. 1).
- "While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification." In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). See, MPEP §2111.01, p. 2100-47 (8th Ed., Rev. 1).
- When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court's analytical process for determining the meaning of disputed claim terms); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)("[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning.") See, MPEP §2111.01, p. 2100-48 (8th Ed., Rev. 1).

The limitation under scrutiny is "and wherein said remote command center further comprises at least one intensivist workstation connected to a computerized patient care management system adapted for proactive monitoring and intervention for individual patients at any of said plurality of geographically dispersed ICU's 24 hours per day, seven days a week, triggered by evidence-based data-driven feedback." The meaning ascribed to this limitation is

not to be gleaned from references that might be applied against it, but rather is to be determined from the claim itself taken as a whole in light of the written description. However, in rejecting the claim inventions, the examiner impermissibly fails in this regard by equating the simple monitoring-alarm systems of the cited references to the rules-based forwarding looking systems disclosed by Applicant.

One unique aspect of the limitation is that the proactive monitoring and intervention is triggered by evidence-based data-driven feedback. The source and nature of this triggering mechanism are certainly relevant to the determination of whether the prior art reads on the limitation as a whole. The written description makes clear that the triggering mechanism utilizes multiple data streams (physiologic data (collected once per minute from the bedside monitors) and all other clinical information stored in the database (labs, medications, etc)) that are processed by a rules engine. The law requires that the claim be read in this context. The equating of the proactive monitoring and intervention aspects of the claimed invention with the single stream monitoring-alarm systems of the cited references simply ignores the law. Applicant submits that when the law of claim interpretation is correctly applied to the pending claims, it becomes clear that neither Buxton nor Reuss teach proactive monitoring.

The examiner acknowledged that Buxton does not teach a medical observer being an intensivist, that the network transmits voice, or that the workstation is adapted for intervention. Additionally, the examiner acknowledged that Reuss does not teach the caregiver being an intensivist. The examiner found these limitations in Lee. However, the examiner also observed that Lee taught against a computerized patient care management system:

> Additionally, Lee teaches that much of the information obtained by the system is not amenable to computerized analysis and thus the observer is essential for interpretation of these data, i.e., the ballistocardiogram, the electrocardiogram, impendance pneumogram and DUSIAP trace must be interpreted by a professional, (the observer or "intensivist") who compares the data to the stored baseline tracings, as well as lung sound requiring human monitoring. Office Action, Paper No. 20, page 7, lines 8-14.

Applicant submits that Lee teaches exactly the mindset that Applicant's disclosure seeks to challenge. It is inherent in Lee's discussion of "2.2 Priorities" in column 8 and "4.1.2 Emergency Diagnostic Session" in column 16 that the system of Lee is only intended to monitor a single patient at a time, as is typically done by physicians with outpatients. According to Lee,

> The Observer will put on "hold" all patients undergoing routine sessions in order to devote full attention to the emergency. Lee, Col. 16, lines 58-60.

It is inconceivable that a single observer, whether a doctor or a trained intensivist, can provide quality care to plurality of acutely ill patients, such as those found in an ICU, if that same observer is charged with monitoring data streams and evaluating the data for patterns indicative of clinical changes in the condition of each of the plurality of patients. The teachings of Applicant's disclosure challenge this old regime by providing automated tools that continuously receive the data collected from an acutely ill patient, correlate disparate physiological indicators, and apply algorithms to determine if the present and projected condition of the patient warrants proactive intervention.

A prima facie case of obviousness as directed to claim 15 of the present invention simply cannot be based on any combination of Buxton, Reuss and Lee. Applicant submits that there is no motivation to combine these references aside from the teachings of Applicant's disclosure, that combining these references is an impermissible exercise in hindsight, and that all three references teach against the limitations of claim 15 of the present invention. Even if Buxton and/or Reuss were found to teach automated proactive intervention, it is still impermissible to combine them with Lee because Lee teaches against automated proactive intervention and the combination "would change the principle of operation of the prior art invention being modified." See MPEP §2143.01 (8th Ed., Rev. 1).

Further, one skilled in the art attempting to solve the problem faced by Applicant would have not motivation to combine Buxton or Reuss with Lee. That is, neither of these combinations addresses the need for providing care for the critically ill that maximizes the presence of an intensivist trained in the care of the critically ill, standardizes the care in ICUs at a high level, and reduces the mortality rate of patients being cared for in ICUs. For all of these reasons, a prima facie case of obviousness as directed to claim 15 of the present invention has not been established.

Assuming that the references may be combined, Applicant submits that neither Buxton or Reuss, with or without Lee, teach the detection of impending problems so that intervention can be initiated before a condition reaches a crisis state (that is, "a computerized patient care management system adapted for proactive monitoring and intervention"). As claim 15 of the present invention recites limitations not taught by the combination of Buxton or Reuss in view

Lee, claim 15 of the present invention is patentable over these references.

Claim 17 of the present invention adds the additional limitation that the computerized patient care management system further comprises a data server/data warehouse for storing and analyzing data from the remote command center. Claim 18 of the present invention adds the additional limitation wherein each of the plurality of geographically dispersed ICU's further comprises patient monitoring equipment electronically connected to the remote command center over the network. As claim 17 and 18 of the present invention depend from claim 15 of the present invention, they recite all of the limitations of claim 15. For this reason, claim 17 of the present invention recites limitations not taught by the combination of Buxton in view Lee, and claim 18 of the present invention recites limitations not taught by the combination of Buxton or Reuss in view Lee. Claims 17 and 18 of the present invention are thus patentable over the cited references.

Claim 19 of the present invention teaches the additional limitation wherein each geographically dispersed ICU further comprises a nurses' station electronically connected to said monitoring equipment and to the remote command center over the at least one network. Claim 19 has been rejected over Buxton or Reuss in view of the examiner's official notice of the "established business practices" of the hospital world. As claim 19 of the present invention depends from claim 15 of the present invention through claim 18 of the present invention, claim 19 of the present invention recites all of the limitations of these claims. Applicant has demonstrated that claim 15 and 18 of the present invention recite limitations not taught by either Buxton or Reuss. For this reason, claim 19 of the present invention is patentable over the cited references.

C. Claim 25 and Claims 21, 22, 24, 26, and 27

Claim 25 of the present invention has been rejected under 35 U.S.C. §103(a) as being unpatentable over Buxton or Reuss in view of Lee as applied to claim 15 and further in view of U.S. Patent 5,724,580 issued to *Levin* et. al (herein, Levin) or U.S. Patent 6,230,142 issued to *Benigno* et al. (herein Benigo). The examiner concedes that decision support algorithms are not taught by either the combination of Buxton and Lee or the combination of Reuss and Lee. The examiner found this limitation in both Levin and Benigno.

Applicant reiterates the arguments directed to the rejection of independent claim 15 and asserts these arguments to the rejection of claim 25. Applicant submits that the references

Buxton, Reuss, and Lee cannot support a prima facie case of obviousness against claim 25 of the present invention. Alternatively, applicant reiterates that neither of these two combinations of these references teaches the limitation "proactive intervention" of claim 25 of the present invention.

The examiner concedes that decision support algorithms are not taught by either the combination of Buxton and Lee or the combination of Reuss and Lee. The examiner found this limitation in both Levin and Benigno. Because the limitation "from decision support algorithms" has been deleted from claim 25 of the present invention as currently amended, the Levitz and Benigno references are no longer relevant.

Claim 21 of the present invention depends from claim 15 of the present invention adds the limitation that the computerized patient care management system further comprises a relational database storing a plurality of decision support algorithms and means for prompting proactive care to patients based upon the any of the decision support algorithms. Claim 21 of the present invention has been rejected for the same reasons set forth for rejecting claim 25 of the present invention. As previously noted, Applicant has demonstrated that claim 15 of the present invention recite limitations not taught by either Buxton or Reuss. Because claim 21depends on claim 15 of the present invention claim 15 is patentable over the cited references.

Claim 22 of the present invention depends from claim 21 of the present invention and recites a list of exemplary decision support algorithms. Claim 22 of the present invention thus recites all of the limitations of claims 21 and 15 of the present invention is allowable for the reasons previously provided with respect to claim 21.

Claim 24 of the present invention depends from claim 15 of the present invention and adds the limitation that the computerized patient care management system further comprises knowledge-based vital sign/hemodynamic algorithms that prompt early, proactive intervention. Again, as claim 24 includes the limitations of claim 15 of the present invention, claim 24 is allowable over the cited references.

Claim 26 of the present invention, as amended, depends from claim 25 and recites that the method further comprises consulting one or more decision support algorithms selected from a list of algorithms for treating various conditions. Claim 26 of the present invention thus recites all of the limitations of claims 25 of the present invention is allowable for the reasons previously provided with respect to claim 25.

Claim 27 of the present invention depends from claim 25 and recites that the method further comprises a data server/ data warehouse storing and analyzing patient data from the command center and providing analysis of results over a second network to the command center. Claim 27 of the present invention has been rejected for the same reasons as claim 17 of the present invention. As claim 27 of the present invention depends from claim 25 of the present invention, it recites all of the limitations of claim 25 and is allowable for the reasons previously provided with respect to claim 25.

D. Claim 23

Claim 23 of the present invention has been rejected under 35 U.S.C. §103(a) as being unpatentable over Buxton or Reuss in view of Lee (as applied to claim 15) in view of Levin or Benigno (as applied to 25) and further in view of U.S. Patent 6,024,699 issued to *Surwitt* et al. (herein, Suwitt). Claim 23 of the present invention depends from claim 15 and adds the limitation wherein said computerized patient care management system further comprises order writing software means for providing knowledge-based recommendations and prescriptions for medication based upon the clinical data.

The examiner acknowledges that Buxton, Reuss, Lee, Levin and Benigno do not teach the order writing software limitation of claim 23 of the present invention. The examiner finds this limitation in Surwitt. While Surwitt describes means for evaluating physiological data for the purposes of rendering a prescription, it does not do so in real-time:

> Patients are responsible for recording data within their PPMs and transmitting the data to a PAC server on a regular basis. Preferably, transmission of data to a PAC server is highly automated and substantially "hands-off" for a patient. A patient preferably can plug a PPM into a standard telephone jack and, with the press of a button, establish communications with a PAC server. Each PPM may have the ability to prompt patients when data transmissions are required, and to initiate and complete data transmissions using an alarm-driven timer. Surwitt, col. 7, line 64 through col. 8 line 6.

By contrast, the order writing software of claim 23 of the present invention is not dependent on the patient transmitting data. Additionally, as claim 23 of the present invention depends from claim 15, claim 23 recites all of the limitations of claim 15 and is allowable for the reasons previously provided with respect to claim 15.

E. Claims 28 and 29

Claim 28 of the present invention depends from claim 15 of the present invention and

adds the limitation wherein the means for transmitting voice and data further comprises transmitting video. Claim 28 of the present invention has been rejected under 35 U.S.C. §103(a) as being unpatentable over Buxton or Reuss in view of Lee (as applied to claim 15) in view of Levin or Benigno (as applied to 25) and further in view of Douglas A. Perednia, Telemedine Technology And Clinical Applications, The Journal of the American Medical Association, Vol. 6, February 8, 1995, pg. 483 (herein, Perednia).

The examiner acknowledges that Buxton, Reuss, Lee, Levin and Benigno do not teach the limitation of transmitting video. The examiner finds this limitation in Perednia, citing the reference for teaching that "more complex applications to telemedicine require one-way or two-way video." The complex applications cited were psychiatric examines and remotely assisted surgery. Perednia further observes that "while the latest and most power equipment may seem logical, the early adoption of two-way full-motion video may be an unrealistic 'gold standard' for many rural and underserved areas. First, although real-time video may not be necessary for many clinical applications, many of the costs incurred by IATV projects are due to the expense of supporting real-time interactions." Perednia, page 5 of 11, last paragraph. Clearly, Perednia is teaching against the limitation of claim 28 of the present invention in which the geographically dispersed ICUs are equipped with video.

As claim 28 of the present invention depends from claim 15, claim 23 recites all of the limitations of claim 15 and is allowable for the reasons previously provided with respect to claim

Claim 29 of the present invention has been rejected for the same reasons as claim 28. Claim 29 depends from claim 25. Applicant reiterates the arguments made with respect to claim 28. Applicant further submits that as claim 29 of the present invention depends from claim 25, claim 29 recites all of the limitations of claim 25 and is allowable for the reasons previously provided with respect to that claim.

F. Secondary Considerations of Non-Obviousness

Even if the prior art references could be properly combined to establish a *prima facie* case of obviousness, Applicants submit that evidence of "secondary considerations" related to unexpected results and long-felt but unresolved needs demonstrate the non-obviousness of the claimed invention.

As submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the application of the present invention has unexpected results with

respect to patient mortality rate, length of stay, average case cost, average case contribution to margin, and monthly contribution to margin as while extending the typical 1:12 ratio of intensivists to patients to a ratio of 1:33 in one published study and as high as 1.83 in current practice.

Unexpected Results

As submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the application of the present invention to the monitoring of a plurality of hospital ICUs resulted in a 27.1% decrease in mortality (from 12.9% to 9.4%) relative to a baseline that *included intensivists*. Although it is known that the participation of an intensivist can decrease the ICU mortality rate, it was unexpected to one of ordinary skill in the art that the addition of the remote monitoring and proactive processing of clinical data of the present invention to such ICUs would result in a further 27% decrease in mortality.

As submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the present invention also decreased the average length of stay (LOS) in the study ICUs by 16.6% (from 4.35 days to 3.63 days). This decrease in LOS is significant given the increasing need for ICU beds and the solution presented by the present invention is non-obvious since many ICUs operate at full capacity, thereby requiring many acutely ill patients to be treated elsewhere in the hospital. Hospitals would surely have implemented such an improvement in throughput/capacity *if it had been obvious.*

As submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the present invention also resulted in a significant decrease in the average case cost of 24.6%.

As submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the system of the present invention resulted in a significant 55.7% increase in the average case contribution margin.

And finally, as submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the present invention resulted in a significant 65.9% increase in the contribution margin per month.

Applicant submits that all of these saving and cost related factors are important since any such significant cost-saving measure would have surely been implemented by hospitals *if it had been obvious*.

Long-Felt But Unresolved Needs

As stated above, it has been recognized that the participation of an intensivist can greatly improve ICU care. The currently recommended ratio of intensivists-to-patients is between 1:8 and 1:12 (multi-patent type unit) and 1:15 (single patient type unit). Despite the knowledge that ICU care can be improved with intensivists, the current intensivist-to-patient ratio has prevented wide adoption of the recommendation due to a lack of trained personnel.

As noted during the course of this prosecution, and as submitted in the accompanying Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz, the present invention decreased mortality, LOS, and costs *while at the same time extending the intensivist-to-patient ratio by greater than 500% to 1:33- 1:83*, thereby greatly assisting in the unresolved need for more intensivists by potentially more than tripling patient access to intensivist-supervised care.

In view of the above information and remarks, Applicant respectfully requests reconsideration of the current rejections. Applicant submits that based on the foregoing, claims Claims 15, 17-19, and 21-59 are allowable over the cited prior art. Applicant further requests that a timely Notice of Allowance be issued in this case. Should any further questions arise concerning this application or in the event the above amendments do not place the application in condition for allowance, Applicant respectfully requests a telephone interview. Attorney for the Applicant may be reached at the number listed below.

Respectfully Submitted,

By _____

Jon. L Roberts
Registration No. 31293
Roberts Abokhair & Mardula, LLC
11800 Sunrise Valley Drive, Suite 1000
Reston, VA 20191
703-391-2900

Attachments: Affidavits of Dr. James Shaffer, Dr. Michael Berman, and Dr. Jeffrey Schwartz